

Information Sheet

Date: May 27, 2011

Subject: FDA Warning against SimplyThick for Premature Infants

Information:

The U.S. Food and Drug Administration (FDA) is recommending that parents, caregivers, and health care providers should not feed the thickening product called SimplyThick to infants born before 37 weeks gestation because it may cause necrotizing enterocolitis (NEC), a life-threatening condition characterized by inflammation and death of intestinal tissue.

Recommendations for Parents and Caregivers

- Do not feed SimplyThick to premature infants (born before 37 weeks gestation), including those in the hospital and those sent home from the hospital within the past 30 days.
- Contact your health care professional if your baby has symptoms of bloating, greenish-tinged vomit, or bloody stools, or if you have other concerns related to using SimplyThick.
- You or your health care professional can report side effects related to using SimplyThick or other thickening agents to FDA's MedWatch Safety Information and Adverse Event Reporting Program by:
 - Completing and submitting the report online: www.fda.gov/MedWatch/report.htm;
 - [Downloading the pre-addressed, postage-paid FDA Form 3500](#) (or calling 1-800-332-1088 to request the form), completing it, and faxing it to 1-800-FDA-0178; or
 - Mailing the completed form to MedWatch, 5600 Fishers Lane, Rockville, MD 20857.